

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/CA05/000358

International filing date: 09 March 2005 (09.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/261,048  
Filing date: 25 October 2004 (25.10.2004)

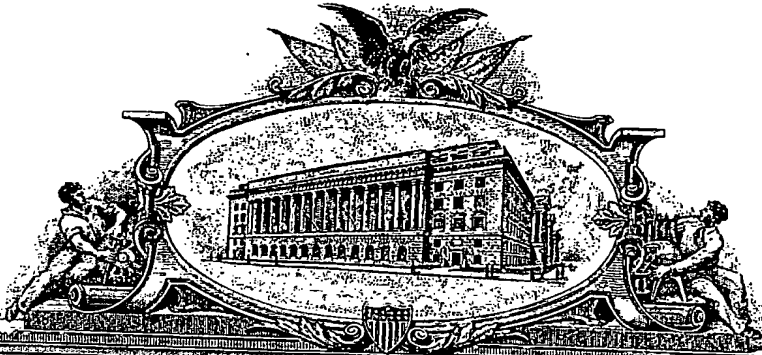
Date of receipt at the International Bureau: 27 April 2005 (27.04.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



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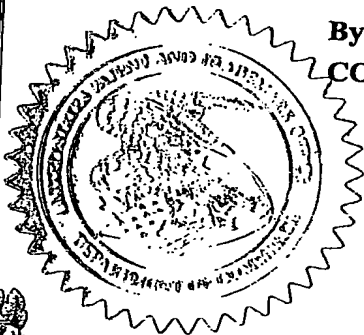
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FILING DATE: October 25, 2004

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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
John		Walmsley		Winnipeg Manitoba Canada	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
SAMPLE COLLECTION DEVICE					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number		CORRESPONDENCE ADDRESS 23529		Place Customer Number Bar Code Label here	
OR					
<input checked="" type="checkbox"/> Firm or Individual Name		ADE & COMPANY			
Address		1700-360 Main Street			
Address					
City		Winnipeg	State	Manitoba	ZIP R3C 3Z3
Country		Canada	Telephone	204-947-1429	Fax 204-942-5723
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		13		<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		10		<input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number		01-0310		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are:					

Respectfully submitted,

SIGNATURE



TYPED or PRINTED NAME Michael R. Williams

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204-957-8364

Date

19/10/04

REGISTRATION NO.

45,333

(if appropriate)

Docket Number:

85408-172

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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P19SMALL/REV08

## SAMPLE COLLECTION DEVICE

### BACKGROUND OF THE INVENTION

Because stool and urine samples can provide valuable information regarding  
5 the health of a patient, medical practitioners often require samples for diagnostic purposes, for example, for detecting metabolite levels, microorganisms or occult blood. For these tests to be accurate, the sample must not be contaminated by toilet water.

Typically, most of the means known in the art for collecting these samples are  
10 inconvenient, embarrassing, complicated, awkward or distasteful. For example:

PCT Application WO 02/058561 teaches a device for collecting stool samples which comprises a collection dish and a support that hooks over the rim of the toilet bowl.

US Patent 5,463,782 teach a stool sample collection which comprises a sheet  
15 of foldable material that is attached by adhesive to the toilet rim such that a cupping section extends down into the bowl.

US Patent 4,445,235 teaches a stool specimen collector that comprises a container suspended in the bowl that is attached to the upper surface of a toilet seat.

US Patent 4,309,782 teaches a stool specimen collector that comprises a bag-  
20 like structure that is beneath the back and side portions of a toilet seat.

US Patent 5,337,426 teaches a stool sample collector which comprises a sheet of flexible material which includes two slits therein which is then fitted over a toilet seat such that the portion of the sheet between the slits extends below the toilet seat.

US Patent 6,640,355 teaches a stool sample collector which comprises a collection structure that rests on the rim of the toilet bowl and has a telescoping arm that extends across the bowl and supports the front portion of the collection structure.

US Patent 6,653,149 teaches a method of collecting a stool sample wherein a  
5 hydrated polymer is added to the water in the toilet bowl prior to use such that the polymer forms a matrix which supports the sample above the water.

US Patent 6,434,762 teaches a stool collecting apparatus comprising a disposable strip which spans the toilet seat region and has a section with an opening for receiving the stool sample.

10 As can be seen, most of these devices must be placed either over or under the toilet seat, which may cause feelings of discomfort or strangeness for the user. Clearly, a device arranged for mounting beneath the seat but either on the rim or bowl of the toilet for collecting stool samples is needed.

15 SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided, in a toilet having a rim and a bowl, a stool sample collection device comprising:

a sample collection platform arranged to receive a stool sample from a user;  
and

20 an end wall extending from the sample collection platform at a right angle to the sample collection platform, said end wall including attachment means for attaching the device to the bowl of the toilet.

According to a second aspect of the invention, there is provided, in a toilet

having a rim and a bowl, a urine and/or stool sample collection device comprising:

a receptacle having a cup arranged to receive urine and a spout extending upwardly from the cup at an acute angle;

a sample collection platform arranged to receive a stool sample from a user,

5 said platform including an opening for inserting the cup therein; and

an end wall extending from the sample collection platform at a right angle to the sample collection platform, said end wall including attachment means for attaching the device to the bowl of the toilet.

10 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an embodiment of the device in breakaway in use within a toilet.

Figure 2 shows the disassembled device.

Figure 3 is a top view of the device.

15 Figure 4 is a side view of the device.

Figure 5 is a front view of the device.

Figure 6 shows an alternative embodiment of the device in breakaway in use within a toilet.

Figure 7 is a perspective view of the device.

20 Figure 8 is a top view of the device.

Figure 9 is a perspective view of the device.

Figure 10 shows the shield of one embodiment of the device.

Figure 11 shows the collector of one embodiment of the device.

Figure 12 shows the base of one embodiment of the device.

Figure 13 shows a top view of the partially assembled device arranged for urine collection.

Figure 14 shows a top view of an alternative arrangement of the partially assembled device.

Figure 15 is a top view of the base in flex position.

Figure 16 is a side view of the base in flex position.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications mentioned hereunder are incorporated herein by reference.

Referring to the drawings, the invention relates to a device 1 for urine sample collection from a female patient and/or stool sample collection. In another embodiment of the invention, the device 2 is arranged for stool sample collection.

Referring to Figures 1-5, a device for urine sample collection from a female patient and/or stool sample collection 1 comprises a sample collection platform 10, an end wall 12 and a receptacle 14.

The collection platform 10 is arranged to collect the stool sample from the user and for insertion of the receptacle 14, as discussed below. Specifically, the collection

platform 10 includes an opening 16 for receiving the receptacle 14.

In the embodiment shown in Figures 1-5, the collection platform 10 further includes a plurality of apertures 18. As will be appreciated by one of skill in the art, the apertures 18 provide for drainage of the sample deposited onto the collection platform

5 10.

In the embodiments shown in Figures 2, 4 and 5, the collection platform 10 has a substantially concave shape which provides stiffness and integrity to the device 1 and also assists in retaining the stool sample on the collection platform 10. This arrangement also provides a three-point stabilized lever.

10 In the embodiments shown in Figures 1-5, the sidewall 12 extends upwardly from the collection platform 10 at a substantially right angle. The sidewall 12 includes attachment means 20 for attaching the device 1 to the side of the rim 102 or bowl 104 of a toilet 100. In the embodiments shown in Figures 1-5, the attachment means 20 comprises two suction cups 22 laterally spaced and connected to the sidewall 12 at

15 positions above the plane of the collection platform 10.

The receptacle 14 comprises a cup 24 and a spout 26. The spout 26 extends upwardly at an acute angle from the cup 24 and has a substantially convex shape for receiving urine thereon. As can be seen from Figures 1-5, the spout 26 is arranged to direct fluid deposited onto the spout 26 downward and into the cup 24, as discussed

20 below. In other embodiments, the receptacle 14 comprises a cup, for example, a disposable cup, for example, a paper cup such as those commonly used with drinking fountains, water coolers and the like. As will be appreciated by one of skill in the art, cups such as these are arranged to hold a suitable quantity of liquid and are also



typically arranged to be disposable.

As discussed above, in the embodiments shown in Figures 1-5, the cup 24 is inserted into the opening 16 prior to use. In other embodiments, the cup 24 may be removably attached to the collection platform 10 such that the cup 24 can be easily  
5 separated from the collection platform 10. In other embodiments, the spout 26 may be connected to the cup 24 such that the spout 26 can be broken off and a lid or cap applied to the cup 24. Alternatively, in some embodiments, the cup 24 may not include a spout.

For use, the device 1 is removed from its packaging and the cup 24 is inserted  
10 into the opening 16. As will be appreciated by one of skill in the art, this is not necessary if the cup 24 was inserted into the opening 16 during packaging. The user may prepare the suction cups 22 for binding, for example, by applying water to the suction cups 22, for example, by dipping the suction cups 22 in the water in the toilet  
15 bowl 104. The user then positions the device 1 proximal to the side of the bowl 104 and applies pressure such that the suction cups 22 engage the bowl 104. In this arrangement, the suction cups 22 adhere to the bowl 104 and the sidewall 12 contacts the bowl thereby forming a stabilizing lever. The female user then sits on the toilet seat 106, positions the spout 26 accordingly (if necessary) and urinates. During urination, the urine travels down the spout 26 and into the cup 24. The cup 24 can  
20 then be removed from the device 1. During defecation, the stool sample is deposited onto the collection platform 10 and held above the level of the water in the toilet bowl. The portion of the stool sample needed for analysis is then removed. It is of note that because the device 1 is mounted beneath the level of the toilet seat and is not

mounted on and does not contact the upper surface of the rim and hence the underside of the toilet seat, the presence of the device is not noticeable to the user.

Referring to Figures 6-9, a device for stool sample collection 2 comprises a sample collection platform 40 and an end wall 42.

5        The collection platform 40 is arranged to collect the stool sample from the user, as discussed below and has a substantially concave shape which provides stiffness and integrity to the device 2 and also assists in retaining the stool sample on the collection platform 40.

10        In the embodiments shown in Figures 6-9, the sidewall 42 extends upwardly from the collection platform 40 at a substantially right angle. The sidewall 42 includes attachment means 44 for attaching the device 2 to the rim 102 or bowl 104 of a toilet 100. In the embodiments shown in Figures 6-9, the attachment means 44 comprises two suction cups 46 laterally spaced and connected to the sidewall 42 at positions above the plane of the collection platform 40.

15        The slope of the toilet bowl 104 picks up the lowest point on the curve of the platform 40 stabilized to receive samples. Vertical points 42 are flexible plastic to work with the suction cups 46.

20        An alternative embodiment of the device is shown in Figures 10-16. Therein, the device comprises a base 200, a shield 220 and a collector 230. As can be seen in Figures 10-16, these components are arranged to be substantially flat for ease of packaging. In some embodiments, the components of the device are molded according to the desired shape in a flat configuration at a desired thickness, for example, 0.845 mm thick, thereby taking advantage of the material's ability to take a

temporary shape that facilitates its functionality, as discussed below, as well as compactness for the purposes of packaging.

Referring to Figure 12, the base 200 comprises a flexing end 201, an insertion end 202, a flap 203, male connector 205 and a plurality of slots:

5        The flap 203 is mounted to the base 200 at a pivot point 204 and includes female connector 206. For assembly, the flap is pivoted about the pivot point 204 and the flexible end 201 of the base is flexed or bent such that the female connector 206 engages the male connector 205, as shown in Figures 15 and 16.

10        The plurality of slots include four insertion slots 210, 211, 212 and 213 for insertion of the collector 230 therein, as discussed below and as shown in Figures 13 and 14, ring slot 208 and shield slot 209.

15        The shield 220 includes a tongue 222 which is inserted into the shield slot 209 and flaps 224 which support the integrity of the device when the tongue 222 is inserted into the shield slot 209. Specifically, the shield 220 is a moisture shield which prevents toilet paper used to remove the stool from the device to the bowl from gathering water, rendering it useless. The shield 220 also includes folds 226, which can be folded downward to keep separation from toilet bowl surface.

20        The collector 230 includes an opening 232, a first end 234 and a second end 236. As can be seen in Figure 11, the opening 232 is closer to the first end 234 than the second end 236. As can be seen in Figures 13 and 14, either the first end 234 or the second end 236 of the collector 230 can be inserted through slots 210, 211, 212 and 213. In the embodiment shown in Figure 14, the collector 230 adds strength and support to the device; in the embodiment shown in Figure 13, the collector is arranged

for urine collection, wherein a collection cup is inserted into the opening 232. As can be seen in Figures 13 and 14, the ends 234, 236 are inserted through the slots such that the collector 230 is effectively "weaved" through the slots, thereby stabilizing the desired confirmation. As discussed above, the collection cup may be a paper cup, for example, a cup similar in shape and size to cups commonly supplied for water coolers, drinking fountains and the like. As will be appreciated by one of skill in the art, these cups are typically arranged to hold a volume of water that is similar to the volume of urine required for sample analysis. Furthermore, these cups are typically arranged to be disposable. It is of note that in some embodiments, a supply of suitable cups may be included with the device, for example, clipped together and inserted into the packaging for the device.

In the embodiments shown in Figures 10-16, the device is assembled as follows. The flexing end 201 of the base 200 is manipulated as discussed above such that the female connector 206 on the flap 203 engages the male connector 205. The shield 220 is then attached to the device by inserting the tongue 222 into the shield slot 209. As discussed above, the flaps 224 support the sides of the base 200, thereby stabilizing and strengthening the device. The folds 226 are folded downward, as discussed above. Next, one end of the collector 230 is inserted into the insertion slots 210, 211, 212 and 213, depending on the intended use. Specifically, as shown in Figure 13, the second end 236 is inserted through the insertion slots 210, 211, 212 and 213 such that the opening 232 extends outwardly from the base 200 for urine sample collection. Alternatively, as shown in Figure 14, the first end 234 is inserted through the insertion slots 210, 211, 212 and 213, thereby stabilizing the device. Next,

suction cups 240, 242 are attached to the base 200. In a preferred embodiment, the suction cups 240, 242 are attached to the base via holes 244, 246 which are within the pivot point 204 and the male connector 205 respectively. Next, rings 248 are fitted onto the ring slot 208. In use, the rings 248 rest against the bowl; thereby further  
5 stabilizing the device.

As will be appreciated by one of skill in the art, the above steps may be carried out in any sequence that results in a suitable device being assembled.

For use, the device 2 is removed from its packaging and if necessary is assembled as described above. The user may prepare the suction cups 46 or 240  
10 and 242 for binding, for example, by applying water to the suction cups 46 or 240 and 242, for example, by dipping the suction cups 46 or 240 and 242 in the water in the toilet bowl 104. The user then positions the device 2 proximal to the bowl 104 and applies pressure such that the suction cups 46 or 240 and 242 engage the side of the bowl 104. The user then sits on the toilet seat 106 and defecates. The stool sample is  
15 deposited onto the collection platform 40 or base 200 and held above the level of the water in the toilet bowl. The portion of the stool sample needed for analysis is then removed. It is of note that the device 2 is arranged such that while using the device, male users may urinate without concerns about contaminating the sample or  
damaging the device as is the case with some of the prior art devices.

20 As will be appreciated by one of skill in the art, the device 1 for urine sample collection from a female patient and/or stool sample collection and the device 2 for stool sample collection may be made of any suitable material, for example, of a plastics material. It is of note that in some embodiments, the device 1 for urine sample

collection from a female patient may be arranged as a disposable device for a single use.

While the preferred embodiments of the invention have been described above, it will be recognized and understood that various modifications may be made therein, and the appended claims are intended to cover all such modifications which may fall within the spirit and scope of the invention.

CLAIMS

1. In a toilet having a rim and a bowl, a stool sample collection device comprising:

a sample collection platform arranged to receive a stool sample from a user;

5 and

an end wall extending from the sample collection platform at a right angle to the sample collection platform, said end wall including attachment means for attaching the device to the bowl of the toilet.

2. The device according to claim 1 wherein the sample collection platform  
10 has a substantially concave shape.

3. The device according to claim 1 wherein the attachment means comprises suction cups.

4. The device according to claim 3 wherein the device includes two suction cups spaced laterally apart on the end wall.

15 5. In a toilet having a rim and a bowl, a urine and/or stool sample collection device comprising:

a receptacle having a cup arranged to receive urine;

a sample collection platform arranged to receive a stool sample from a user, said platform including an opening for inserting the cup therein; and

20 an end wall extending from the sample collection platform at a right angle to the sample collection platform, said end wall including attachment means for attaching the device to the bowl of the toilet.

6. The device according to claim 5 wherein the sample collection platform

has a substantially concave shape.

7. The device according to claim 5 wherein the attachment means comprises suction cups.

8. The device according to claim 7 wherein the device includes two suction  
5 cups spaced laterally apart on the end wall.

9. The device according to claim 5 wherein the cup includes a spout extending upwardly from the cup at an acute angle



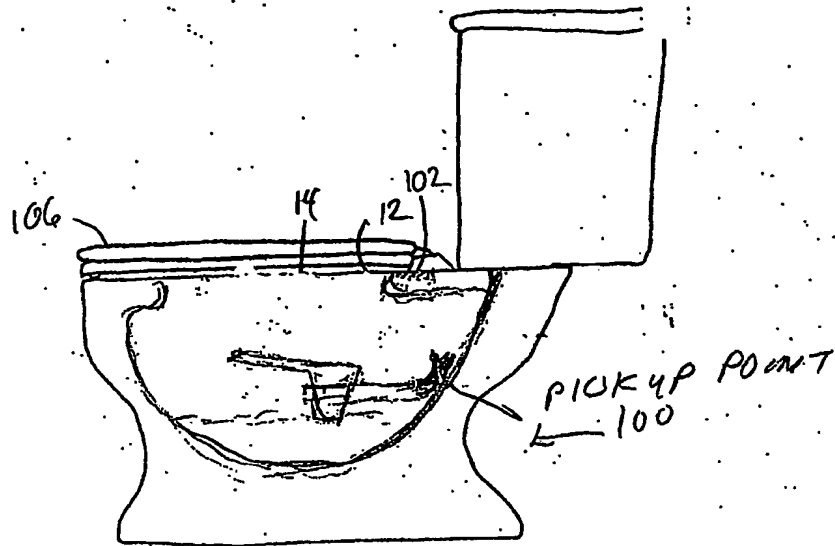


FIG. 1

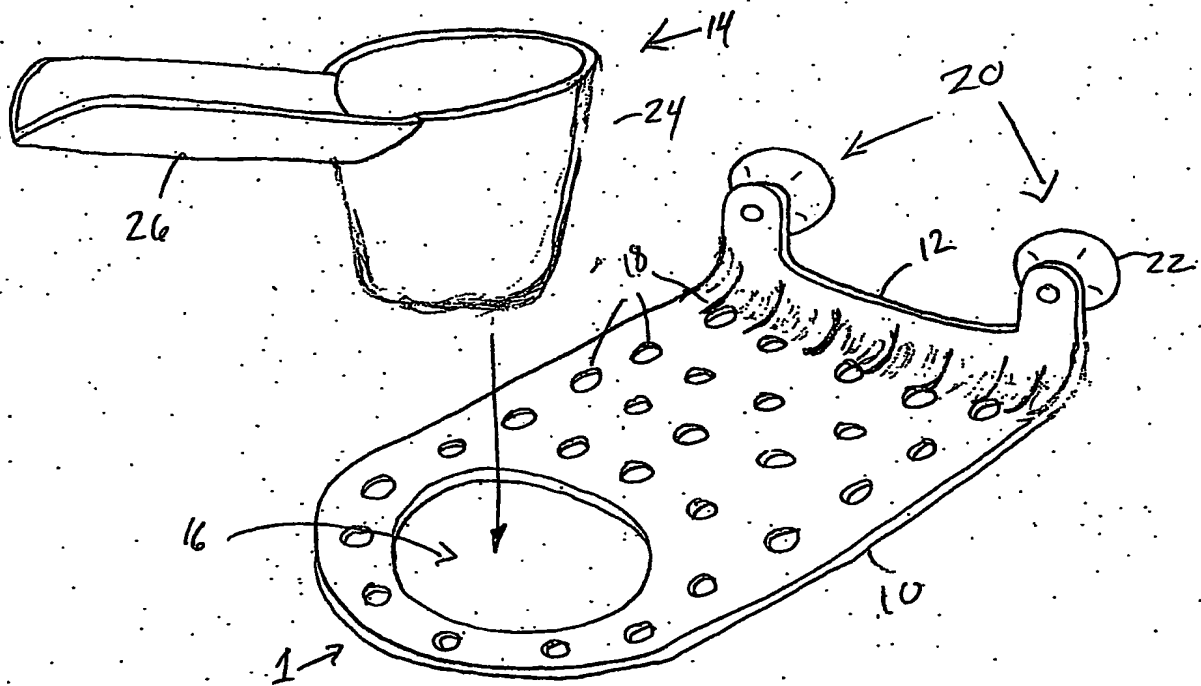


FIG. 2

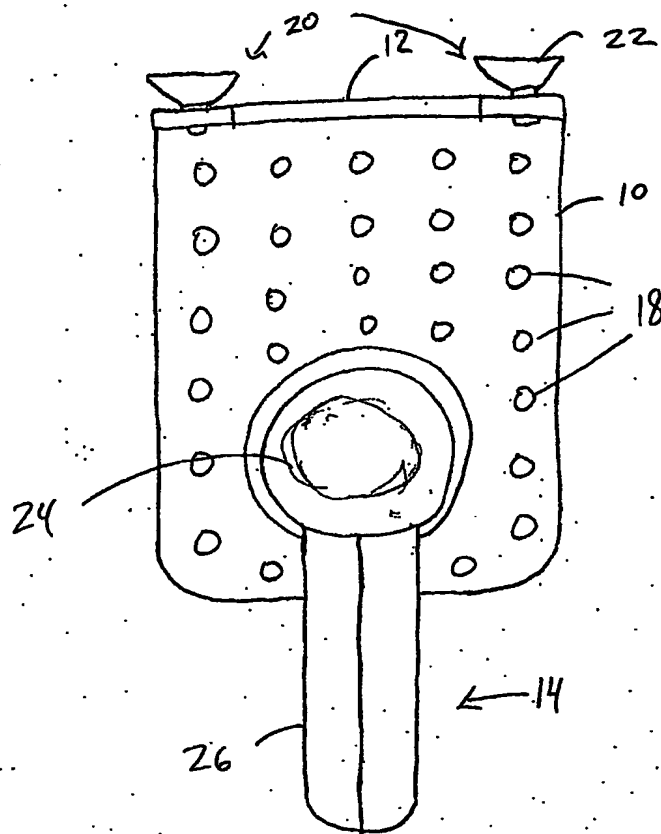


FIG. 3

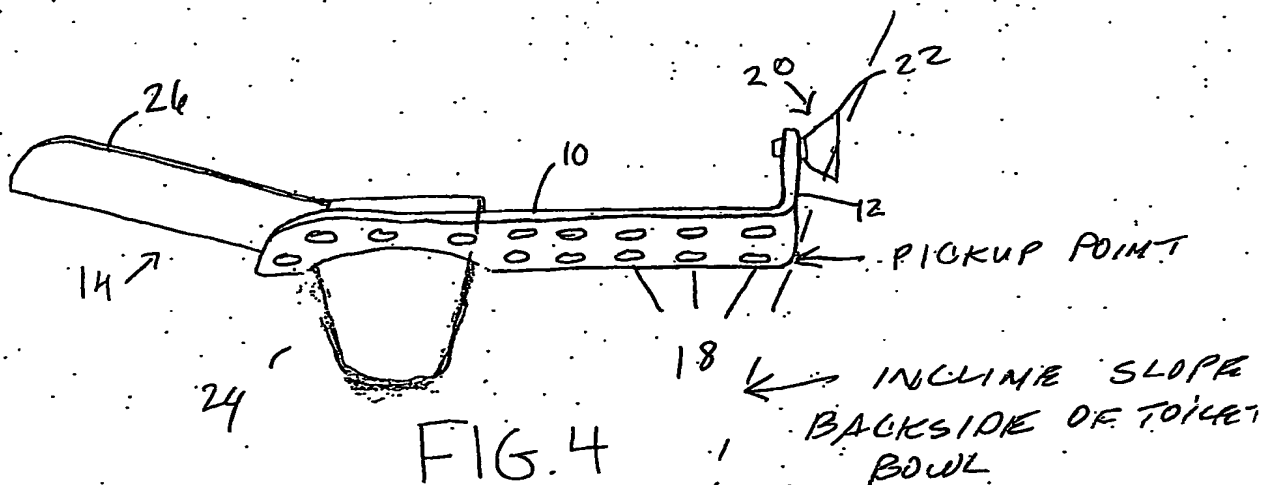


FIG. 4

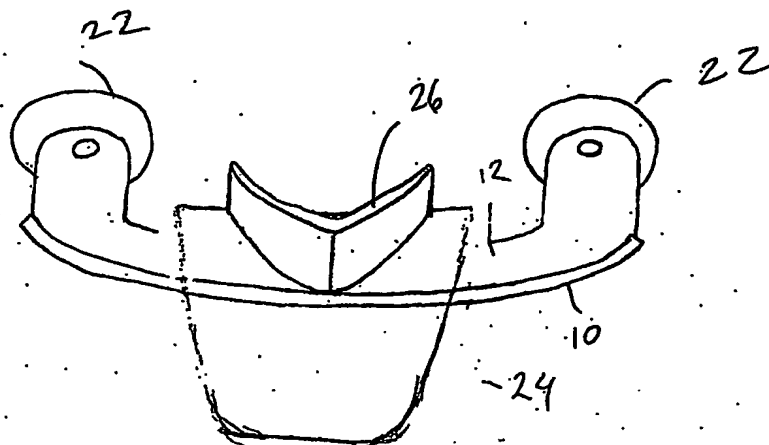
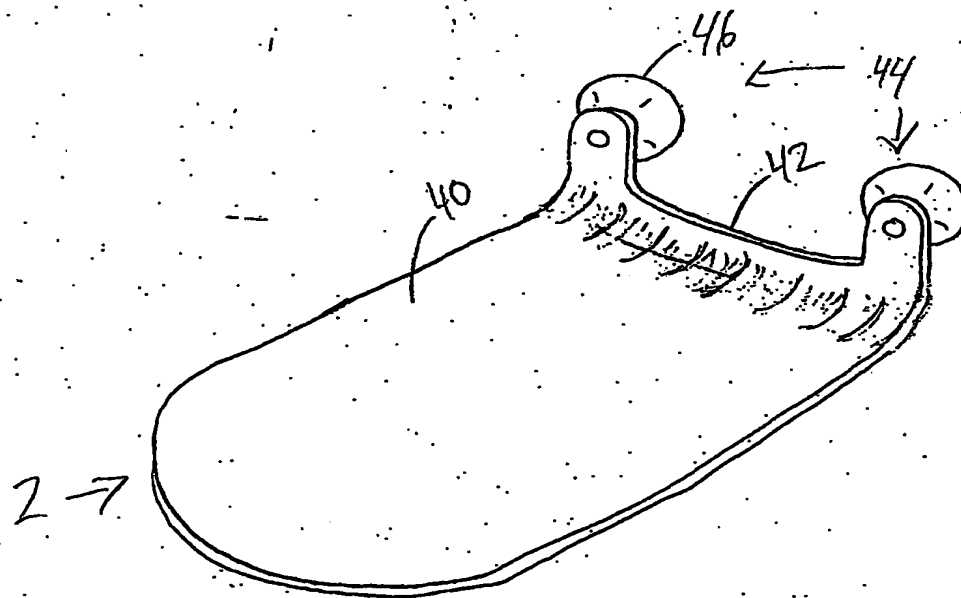
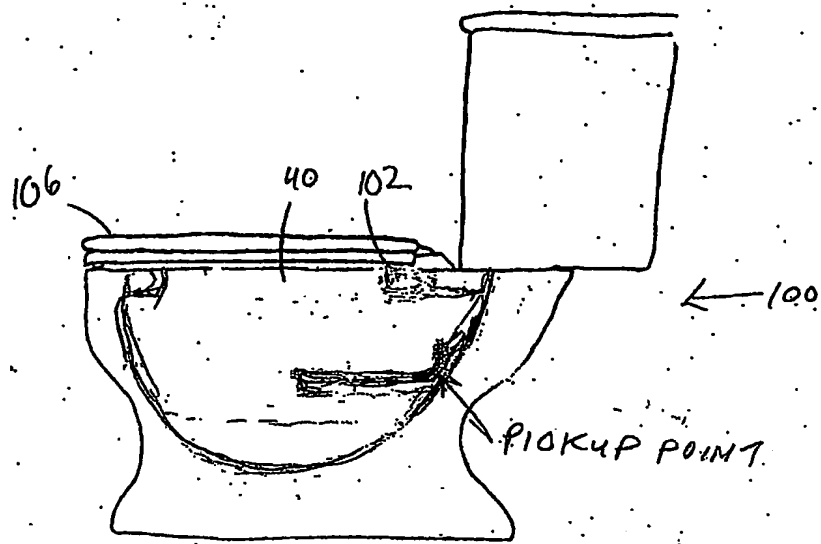


FIG. 5



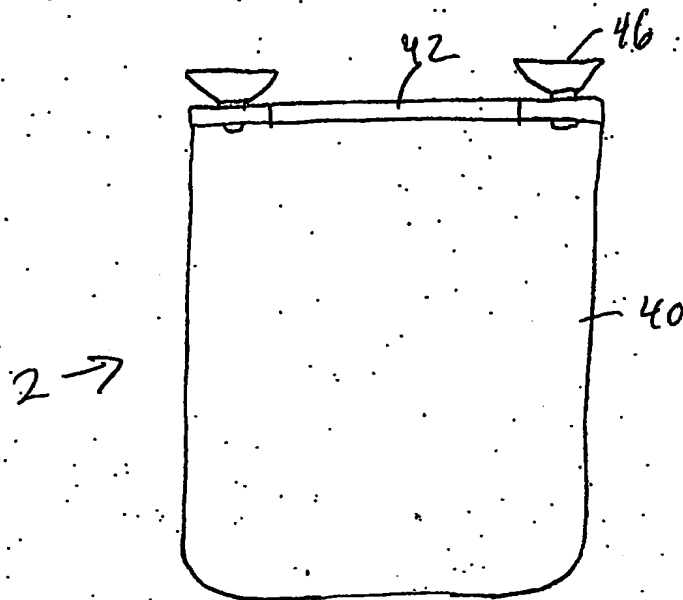


FIG. 8

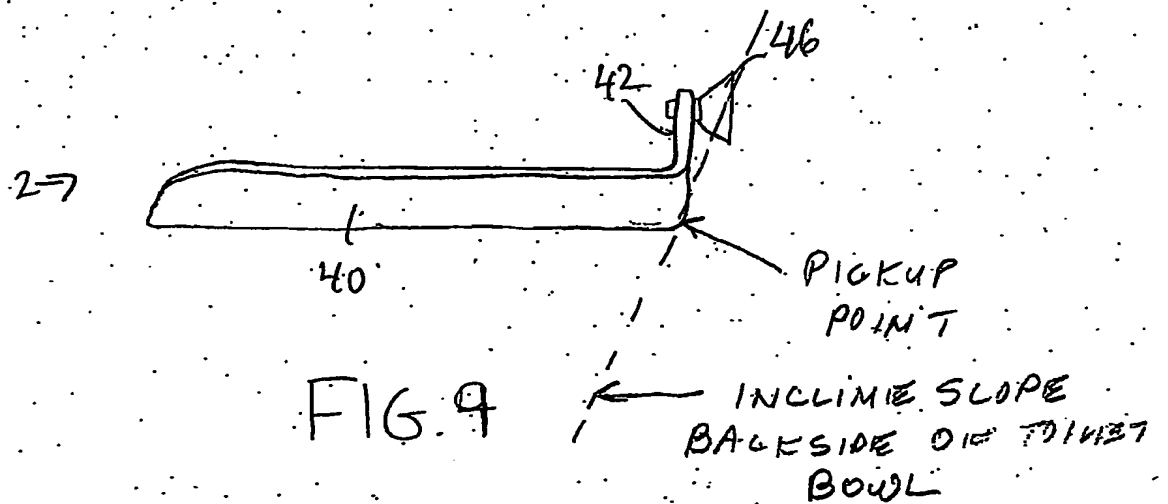
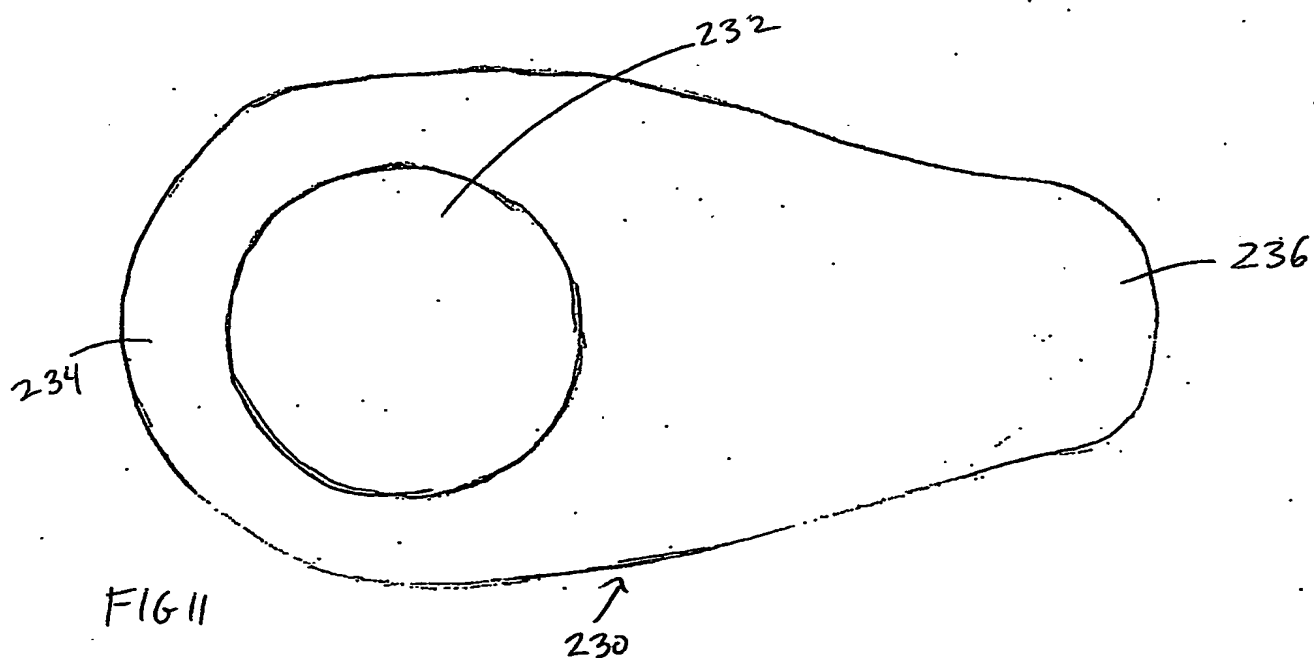
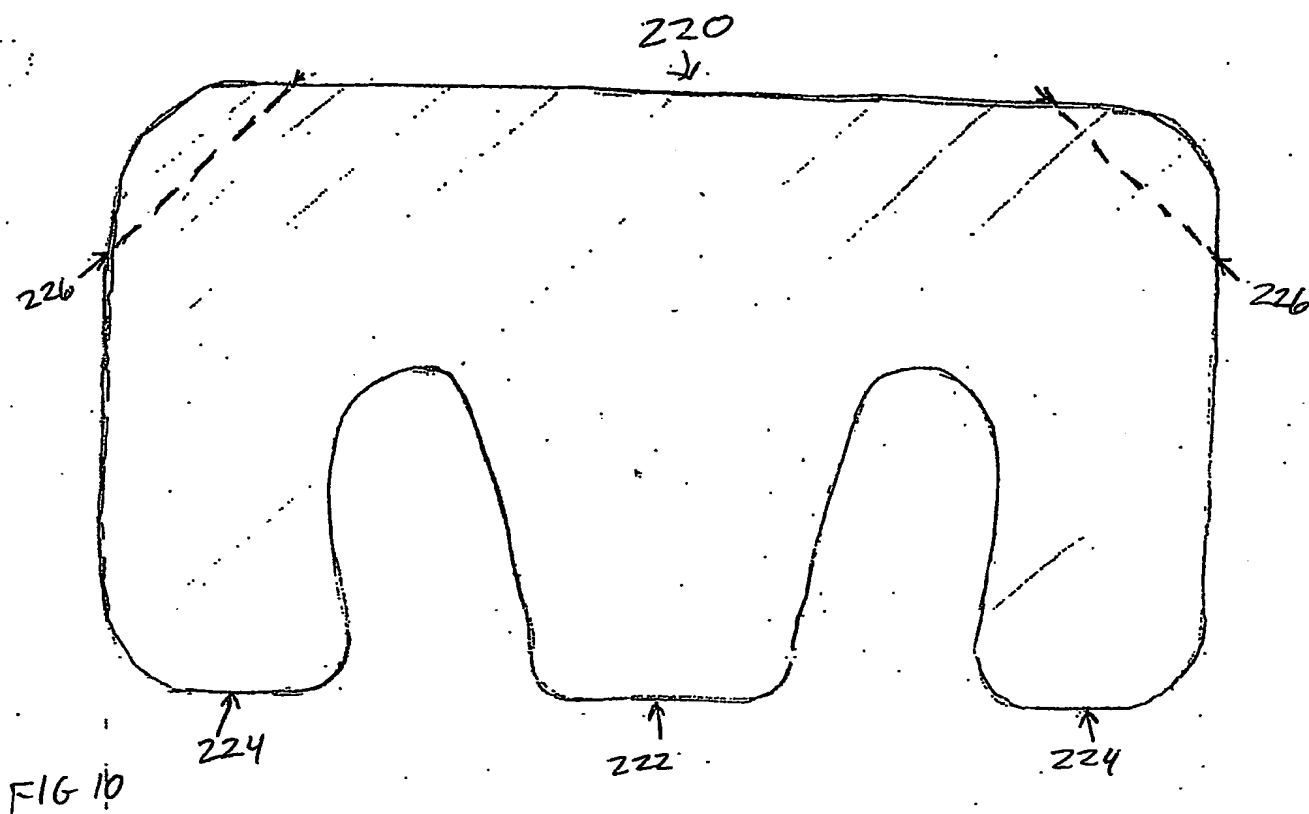


FIG. 9



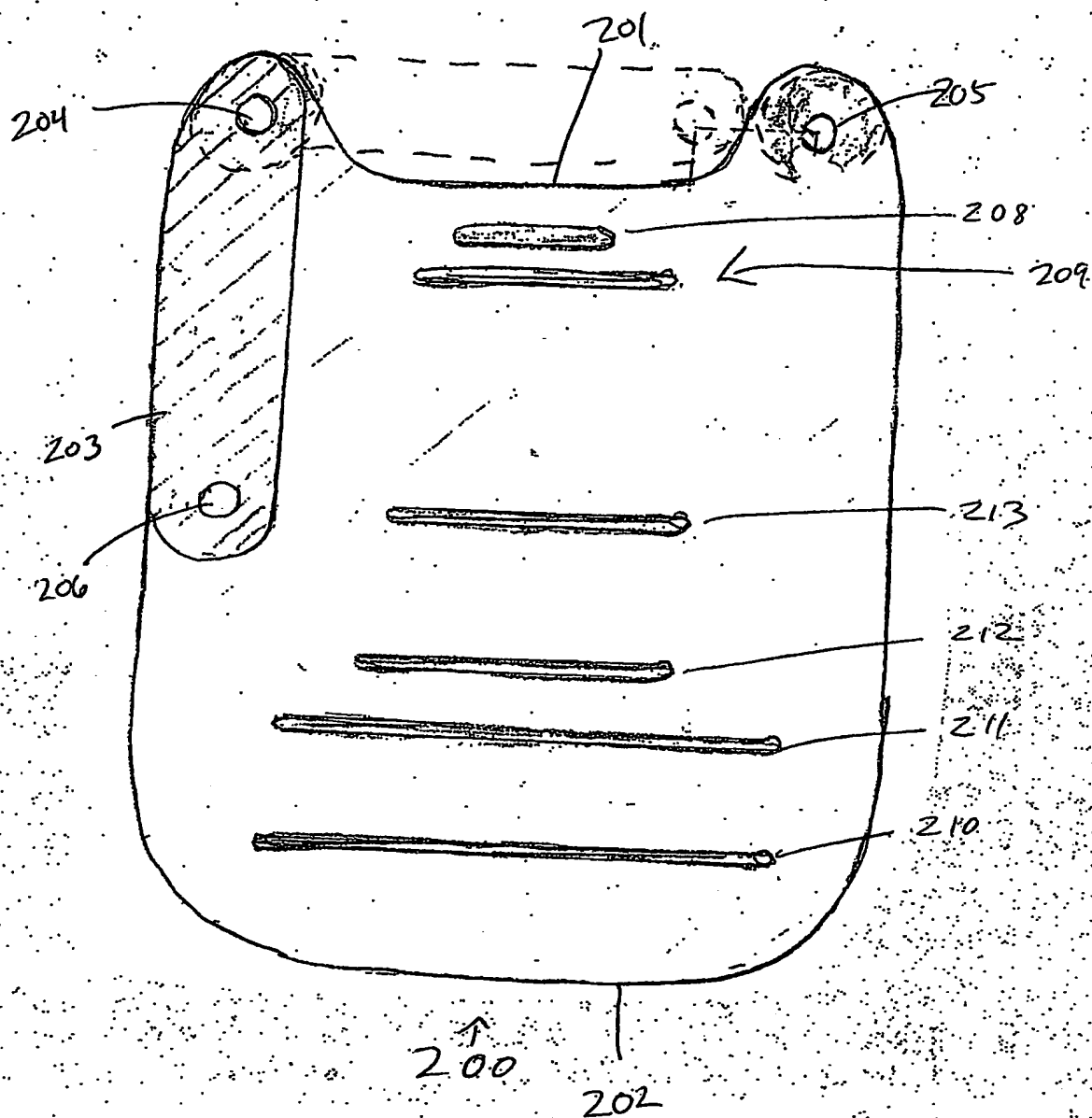
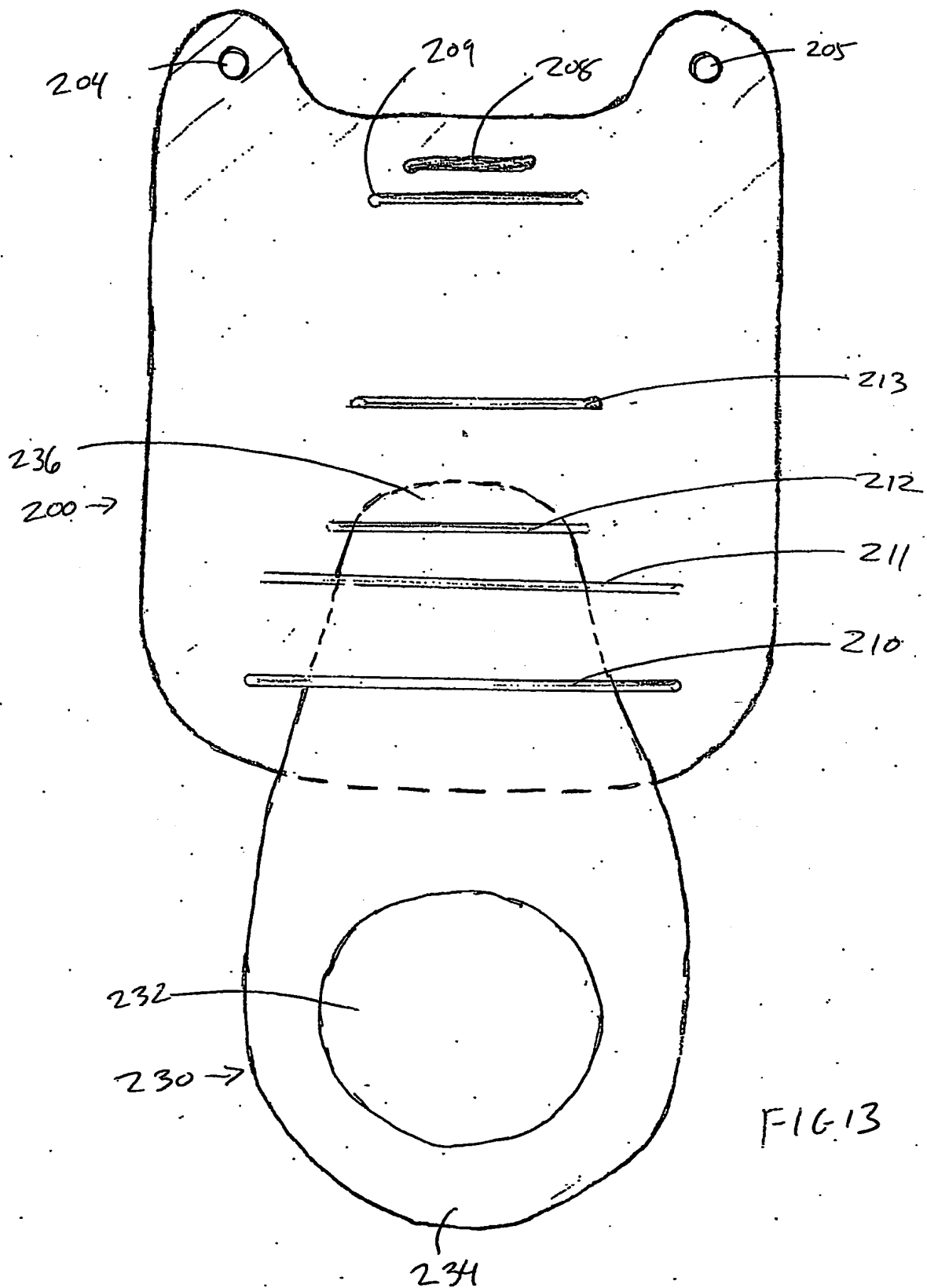


FIG 12





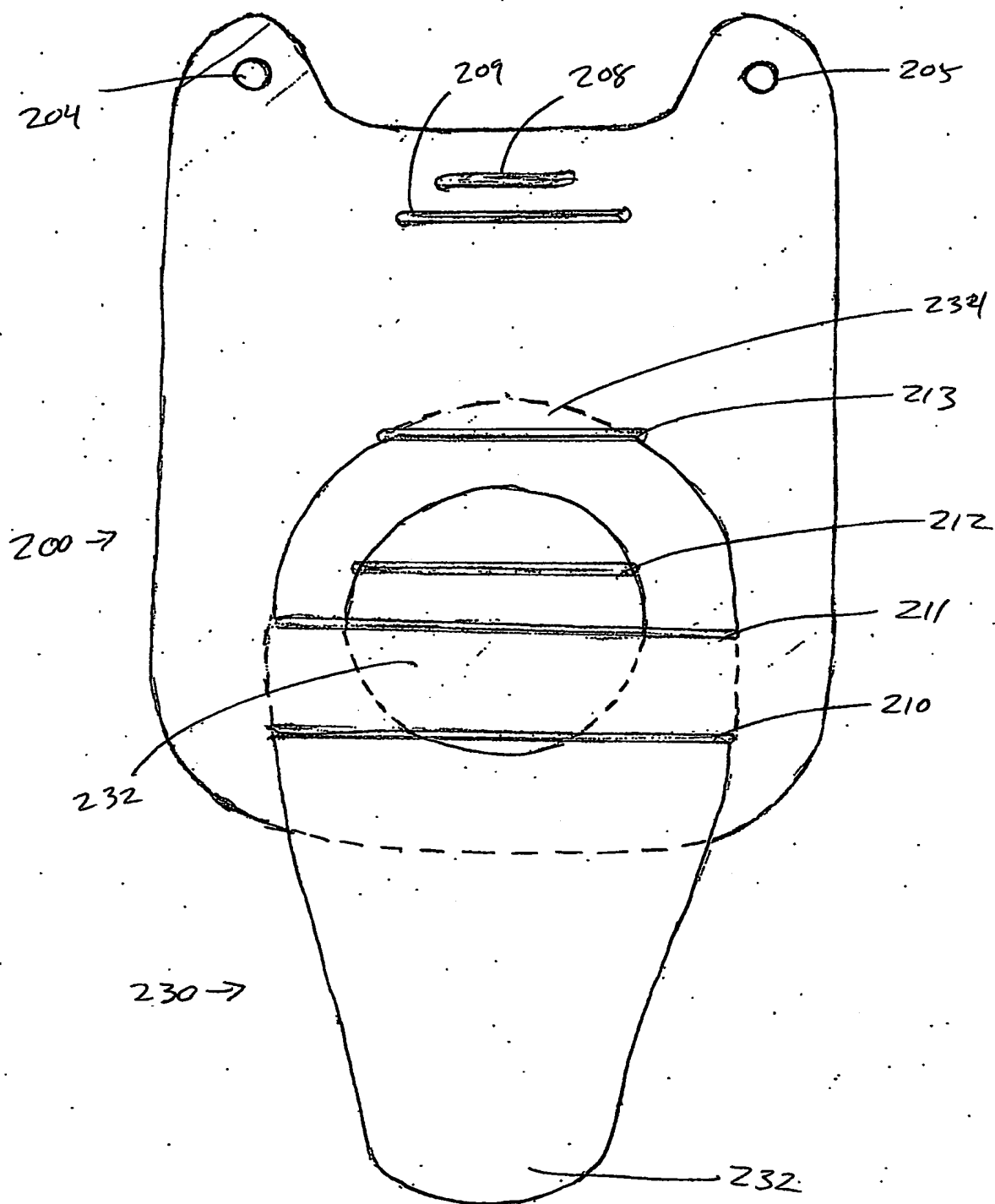


FIG 14

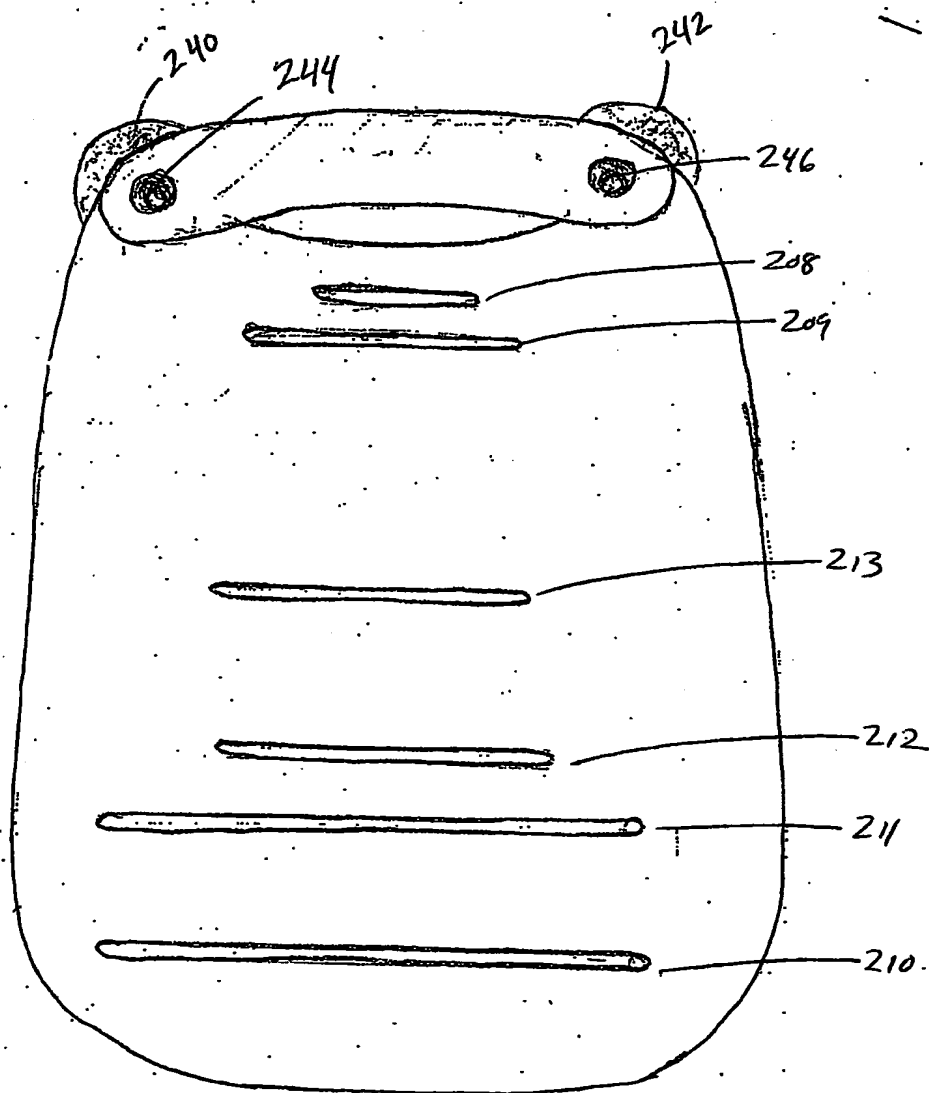


FIG. 15

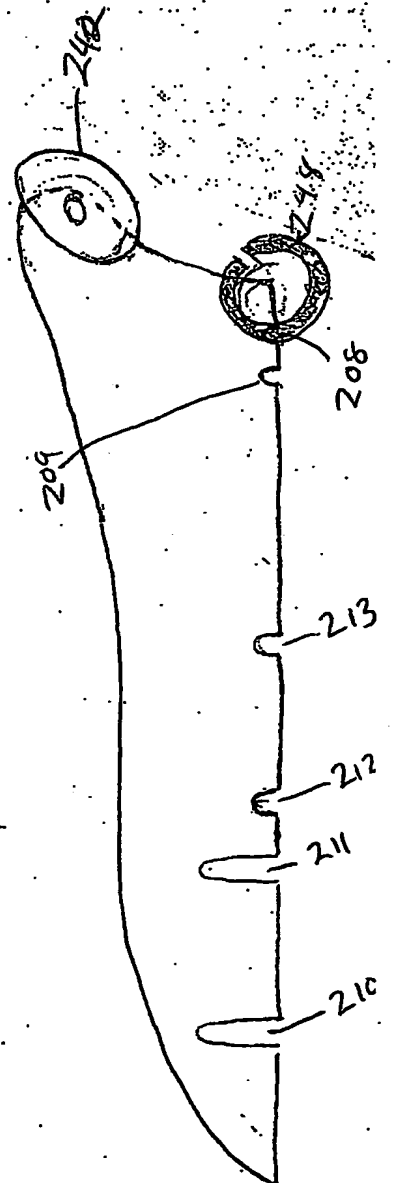


FIG. 16